

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 20-114/S006

APPROVAL LETTER

HIGHLY CONFIDENTIAL -

PLAINTIFFS'
TRIAL EXHIBIT
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N20114

Wallace Laboratories, Division of Carter-Wallace, Inc.
Half Acre Road
P.O. Box 1001
Cranbury, NJ 08512-0181

SEP 15 2000

Attention: George R. Hemsworth, Ph.D.
Director, Regulatory Affairs

Dear Dr. Hemsworth:

Please refer to your supplemental new drug application dated November 10, 1999, received November 15, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Astelin (azelastine hydrochloride) Nasal Spray.

We acknowledge receipt of your submissions dated February 11, July 13, and August 30, 2000.

This supplemental new drug application provides for the use of Astelin Nasal Spray for the treatment of symptoms of vasomotor rhinitis in adults and children 12 years of age and older.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text and with the minor editorial revisions listed below. Accordingly, the supplemental application is approved effective on the date of this letter.

Revise the Dosage and Administration section of the package insert as follows.

DOSAGE AND ADMINISTRATION

Seasonal Allergic Rhinitis

The recommended dose of Astelin® Nasal Spray in adults and children 12 years and older with seasonal allergic rhinitis is two sprays per nostril twice daily. The recommended dose of Astelin® Nasal Spray in children 5 years to 11 years of age with seasonal allergic rhinitis is one spray per nostril twice daily.

Vasomotor Rhinitis

The recommended dose of Astelin® Nasal Spray in adults and children 12 years and older with vasomotor rhinitis is two sprays per nostril twice daily.

The final printed labeling (FPL) must be identical with the minor agreed upon revisions indicated above, to the submitted draft labeling (package insert submitted August 30, 2000). These revisions are terms of the approval of this application.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-114/S-006." Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27) for children below 5 years of age. We are deferring submission of your pediatric studies until September 14, 2002. However, in the interim, please submit your pediatric drug development plans within 120 days from the date of this letter unless you believe a waiver is appropriate. Within approximately 120 days of receipt of your pediatric drug development plan, we will review your plan and notify you of its adequacy.

If you believe that this drug qualifies for a waiver of the pediatric study requirement, you should submit a request for a waiver with supporting information and documentation in accordance with the provisions of 21 CFR 314.55 within 60 days from the date of this letter. We will notify you within 120 days of receipt of your response whether a waiver is granted. If a waiver is not granted, we will ask you to submit your pediatric drug development plans within 120 days from the date of denial of the waiver.

**APPEARS THIS WAY
ON ORIGINAL**

Pediatric studies conducted under the terms of section 505A of the Federal Food, Drug, and Cosmetic Act may result in additional marketing exclusivity for certain products (pediatric exclusivity). You should refer to the *Guidance for Industry on Qualifying for Pediatric Exclusivity* (available on our web site at www.fda.gov/cder/pediatric) for details. If you wish to qualify for pediatric exclusivity you should submit a "Proposed Pediatric Study Request" (PPSR) in addition to your plans for pediatric drug development described above. We recommend that you submit a Proposed Pediatric Study Request within 120 days from the date of this letter. If you are unable to meet this time frame but are interested in pediatric exclusivity, please notify the division in writing. FDA generally will not accept studies submitted to an NDA before issuance of a Written Request as responsive to a Written Request. Sponsors should obtain a Written Request before submitting pediatric studies to an NDA. If you do not submit a PPSR or indicate that you are interested in pediatric exclusivity, we will review your pediatric drug development plan and notify you of its adequacy. Please note that satisfaction of the requirements in 21 CFR 314.55 alone may not qualify you for pediatric exclusivity. FDA does not necessarily ask a sponsor to complete the same scope of studies to qualify for pediatric exclusivity as it does to fulfill the requirements of the pediatric rule.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

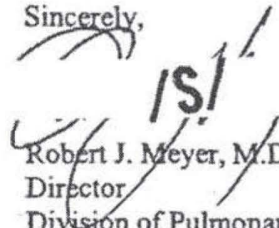
MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Ms. Gretchen Trout, Regulatory Project Manager, at (301) 827-1058.

Sincerely,



Robert J. Meyer, M.D.

Director

Division of Pulmonary and Allergy Drug Products

Office of Drug Evaluation II

Center for Drug Evaluation and Research

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